# NEW YORK STATE VEGETABLE GROWERS ASSOCIATION, INC.

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97N-0451

December 18, 1997

Dockets Management Branch (HFA-305)
Food & Drug Administration
12420 Parklawn Drive - Rm 1-23
Rockville, MD 20857

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RE: Docket #97N-0451

This is to convey some of our comments and concerns about the November 25 draft *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.*

Obviously, you feel these *Guidelines* are necessary. We say fine, **as long as they remain guidelines only.** However, we think what is really needed is guidelines for consumers.

We were stunned that you gave us such short notice of the "grassroots" public meetings and no advance *Guidelines* to comment upon until the actual meetings in Michigan and New York – and then such a short comment period afterward. This reflects poorly on the public relations of the FDA. It would have been far more constructive and far-sighted to do otherwise, both from a scientific as well as a smarter political viewpoint.

We are dismayed these guidelines are being rushed into regulations for apparently political reasons. And without much knowledge about the enormous diversity and complexity of our produce industry. It is far more preferable to keep these as voluntary guidelines only, and for the USDA and the land grant universities to augment them with research and/or administer them as educational programs. This would allow for the huge differences in regional crop production practices and be more practical for all concerned.

**How can you make these *Guidelines* help us?** With all the other regulations being imposed upon agriculture in recent years, many U.S. growers are wondering just whose food consumers will be eating in the years 2000+. It may not be from the U.S. The recent blanket announcement by FDA to ban Guatemalan raspberries in this country for 1998 before they even have a crop is not a good omen for these *Guidelines* and our industry. Does this mean that one cider problem in New York will cause all cider in New York to be banned from sale? Is it possible that a food scare based on pathogens *suspected* in a manure application will cause produce buyers to refuse *any* produce grown on fields where manure is applied? (It can happen. While the scenario was different, there were a great many apple growers who could not sell one apple after the Alar blow-up, even when the most of growers did not use it. It was devastating to the apple industry and it took several years for apple growers to recover; some never did and never will.)

We are anxious to see the second draft *Guidelines* and learn that your office has listened to our industry concerns. Our concerns are very real, we can assure you.

Sincerely,

Larry Eckhardt

Lawrence Eckhardt
President

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**Comment #1 – Our food is among the safest in the world.**

The major foodborne illnesses have been associated with produce from other countries with far more serious food sanitation and production problems. We have always a vested interest in doing the best we can. Our growers' ability to stay in business depends on safe produce for their customers – and with a very few exceptions, our industry has done it extremely well for a great many years.

It is crucial that consumers continue to have confidence in our crops – and know that eating fresh fruits and vegetables is the most important thing they can do for their health and well-being. With most of the public's education/information now coming from the often ill-informed and misguided news media, caution and science on the part of the FDA and other agencies in handling real food problems is even more crucial. A zero-tolerance approach to reducing food pathogens in produce is not realistic, given the complicated and lengthy process of getting food from the field to fork, with all the unknowns along the way.

**Comment #2 – The consumer's food handling education.**

Many of the food illness problems could be solved by the consumers properly cooking and/or washing produce. There is very little consumer education on proper food handling these days – and there are many hands, bags/boxes, time in the warm car, etc. between the purchase and the eating. The news media usually only reports the latest horror stories – with little if any educational information.

Food handling/cooking classes are no longer taught in schools, other than kids being told to wash hands after using the restroom. In most school districts, the elementary students do not even have an opportunity to wash their hands before lunch. The "women's" magazines rarely have any information unless it has to do turkey handling at Thanksgiving or mayonnaise in the summer. Food magazines these days focus on the fat/sodium/caloric content of food or recipes, with few if any on food handling safety. Consumers are cooking less now; *warming* something in the microwave is more the norm. Nor are consumers reminded to clean their refrigerators or check temperatures. Even Cooperative Extension has re-focused to "food security" and nutrition issues.

How far does industry have to go to protect consumers from themselves? Who is there to help protect the food producers and retailers from the consumers? It is very telling of the times that it wasn't so long ago that finding a worm in an ear of sweet corn meant just cutting it out and eating the corn. But now, upon occasion sweet corn with a worm is returned to the supermarket as if it were a defective product.

**Comment #3 – Control of wildlife in production areas.**

As you are well aware, wildlife control of any kind is nearly impossible – and with animal rights activitists getting noisier, any wildlife control in itself is becoming controversial.

Our industry will continue to try to minimize wildlife in fields and orchards for food safety as well as for economic reasons, but we cannot control what the consumer walks through while tending the home garden, filling the birdfeeders or sits in while at the park feeding the ducks.

**Concern #4 – Water quality.**

Most producers have little control over water quality for field use. Many don't have more than one water source. Trickle irrigation might lessen potential contamination (although we still need good research on this), but growers can't afford to grow most crops with trickle irrigation at an extra $4 up to $500 per acre. And most growers can't switch from one irrigation source to

*(more)*

another.

Having water tested before irrigation isn't realistic – growers will go broke paying for tests. Plus, testing of water takes several days at least and in the meanwhile the crop has been irrigated or the tested stream water is long gone into another area. Does this mean that the operation must cease while a perceived problem is resolved – particularly if the FDA enforcement agency opinion differs from the local health department?

If the creek water can't be used on food crops or in the packinghouse, then why not also restrict fishing or swimming in the same source as well? How do you keep the deer and wildfowl out of the creek? And, it is one thing to resolve a runoff problem with the dairy farm up the creek, but getting upstream neighbors to deal with their problematic septic systems more often is a different issue. These guidelines/regulations must not make the grower responsible for solving these problems.

**Concern #5 – Crop-specific practices.**

This area is frought with problems for *Guidelines*. Many growers produce a variety of crops throughout their season – some as many as 30-40. Cultural practices vary greatly from field preparation to planting, to harvest. Handling in the field, during the packing process (whether in the field or shed), demands different attention, crews, packing boxes/cartons, cooling procedures, etc.

One size definitely will not fit all. Again, aseptic conditions for many crops being handled simultaneously by growers at peak season become become nearly impossible. *Guidelines* being considered are not feasible and should be discouraged or at best, postponed.

Traceback or "positive lot identification" procedures in general are a known to growers, but not necessarily documented as such. The practicality of the documentation process needs further examination.

**Concern #6 – Worker sanitation and field hygiene.**

While many of these guidelines are common sense and already in widespread use by growers in the field as well as the packinghouse, you make one erroneous assumption – <u>there is no consistent agricultural workforce in our industry</u>. Every growing season, our growers are faced with a LACK of workers along withunrealistic labor laws. It is a real obstacle to keep up with the field sanitation training of workers who are in fear of being taken away by the INS on a moment's notice. Part of the workforce needs this industry has is not only a predictable supply of workers but also one that is experienced and trained. Until our legislators, the U.S. Dept. of Labor and INS resolve this, it will continue to present major production difficulties. (How well would the FDA function if it had to re-hire and re-train most of its workforce every year?)

**Concern #7 – Manure use.**

Animal manure has been used for thousands of years by agriculture on crops. While its use declined in this century, we have seen increased use since the late 1980s thanks to practices encouraged by land grant universities, cooperative extension, the federal SARE program. Some growers have even invested in dairy/beef operations to get a local manure source. Manure use is viewed as a good soil improvement practice now, since not all soils are created equal.

Manure is applied and incorporated before planting vegetable crops – this ensures that at least 60 days pass from application to harvest, probably much longer depending on the crop. Requiring growers to have a 120+ delay would result in manure applications at times (such as in the late fall or winter when the ground is frozen) and nitrogen would be lost through leaching or

runoff into surface water, creating other problems.

Treating manure chemically or physically (composting) is expensive and most growers would or could not do this.

We are unaware of any New York growers using municipal sewage sludge.

More good research needs to be done on manure applications on vegetables, the food pathogens in question, and options for growers. Giving the produce buyers a reason (real or imagined) to reject produce based on non-science would have a terrible impact on our industry.

**Concern #5 – Post-harvest handling.**

The goal of every vegetable grower is to remove field heat from vegetables. The idea of washing vegetables in water 10-degrees warmer than the produce goes against everything the grower is trying to do to maintain quality. No one will do it. Poor quality produce doesn't sell.

Chlorination of wash water is the industry norm – and should continue to be encouraged in that it helps to eliminate pathogens and will control rotting organisms that decrease quality. But plan to suggest another practical chemical since there is a strong movement at the federal level to ban uses of chlorine.

The trip from farm to supermarket is frought with handling problems. While the trucks that are used are clean, they aren't sanitized, and tracking what happens to produce – especially when mixed loads are shipped – is extremely difficult, even without knowing what happens in the unloading process at the distribution end.

**Concern #6 – The diversity of our farms and markets.**

How will these *Guidelines* help us (especially if they become regulations without any realistic, planned educational component)? Where will this leave our growers – whether large, medium or small – who will have still another layer of regulations and enforcement personnel at their door.

How, for example, will the Community Supported Agriculture farms (CSAs), the U-Pick operations, and other variations on these marketing themes implement these *Guidelines*?

Again, one size will not fit all for U.S. growers. For example, New York has one, relatively short growing period from late March (if we are lucky) through September (if we don't get an early frost on crops affected by it) or October/November (depending on freezing temperatures and snow). Our growers put in 12-16 hour/7-day-a-week workdays during this season. They produce everything in six months that growers in western or southern states have most of a year to do. Our cultural practices are quite different, as are our soils, plant diseases and pest problems, harvest/handling and transportation.

U.S. consumers are now, more than ever, eating food from all over the world, and not by choice whether they realize it or not.

Right now, we rank about 5th in the nation in vegetable production. Our best guess is that about 5-8% of our produce grown in this state, stays in this state – the rest is shipped up and down the East Coast and out as far as the Midwest.

However, our markets are slowly being lost to other countries with very different production practices and cheaper workforces. Our growers say that they are selling food at 1974 prices, but with 1997 expenses. The produce industry does not have a level playing field.

Our growers are as anxious as anyone else to continue to provide safe, clean produce. But how can the additional work and attention to these *Guidelines* (or later regulations) recoup the expenses involved or help us stay in business? How can these *Guidelines* improve our markets or open up new ones for us?

*(end)*

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December 19, 1997

Dockets Management Branch (HFA - 305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

Re: Docket No. 97N-0451: Microbial Safety of Produce: Grassroots and International Meetings

We appreciate the opportunity to comment on the President's initiative to ensure the safety of imported and domestic fruits and vegetables and other foods, announced October, 2, and specifically on FDA's "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (hereinafter referred to as "the guide"). We support the intent of the initiative and recognize that foodborne disease is a serious national health issue. The United Fresh Fruit and Vegetable Association supports action to reduce the incidence of foodborne illness and is not opposed to federal guidance if it is developed at an appropriate pace, using a methodical, science based approach, in concert with a broad spectrum of industry experts. We look forward to working cooperatively with FDA and USDA to bring the President's initiative to a successful reality.

The following points summarize United's key concerns with the President's initiative and FDA's "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables:"

**GENERAL COMMENTS**

1. *Guidance is preferred over regulation because it affords the industry and the Agencies flexibility.* Given the lack of concrete information upon which to base recommendations and the complexity and diversity of the industry, guidance is an appropriate, effective response. Also, guidance, not regulation, will have the flexibility to accommodate the necessary science, as it becomes available.

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2. *While this is guidance, buyers of fresh produce will use it as a standard on which to base their purchasing agreements, making it de-facto regulation.* We urge FDA to recognize this in moving forward and insure that sufficient language is included to minimize misinterpretation of any recommendations. After all, there may be many reasons to depart from this guidance, given the industry complexity.

3. *The current pace threatens to jeopardize produce industry participation and ignores the complexity of our industry.* The industry urges FDA and USDA to convey to the Administration that more time is necessary to produce guidance that portrays what is practical, reasonable and based in sound science.

4. *Any guidance developed by the U.S. Food and Drug Administration and U.S. Department of Agriculture for the produce industry, must be based on sound science and reasonable information.* Federal guidance cannot impose prescriptive, arbitrary, recommendations. Instead, the agency must limit the scope of guidance and policy to what is known. To the extent that any recommendations are grounded in sound science the industry will support them.

   The industry welcomes education about any risks associated with agricultural and handling practices, and is quick to adjust when science warrants. However, industry operators should not be unjustly burdened because scientific information lags behind epidemiological evidence, forcing compliance with ungrounded recommendations.

5. *Commodity specific guidance is unnecessary. Broad industry guidance is sufficient to prevent food safety problems.* Instead of focusing government resources on developing commodity-specific guidance we recommend that industry and government work in partnership, through a Memorandum of Understanding, to develop education and outreach programs based on broad FDA guidance. It is under this cooperative framework that we, together, can make a true impact on public health. After all, results, not words, will give consumers confidence.

6. *Good Agricultural Practices and Good Manufacturing Practices are appropriate for assuring the safety of whole commodities, NOT Hazard Analysis and Critical Control Point programs.* HACCP is a food safety system grounded in science. Because the scientific understanding of what gives rise to contamination of produce is very limited, HACCP is an inappropriate regulatory response.

7. *Additional meetings throughout the industry, including field tours, are essential before completing the development of broad industry guidance.* The current haste with which the initiative is moving forward prohibits those drafting guidance from gaining an adequate understanding of current industry practices and regulations, jeopardizing any federal guidance effort. Additional meetings are necessary in California, Texas, and other states to accommodate industry feedback. Field tours are also an essential part of understanding industry challenges and complexities. We urge the Agencies to capitalize on our offer to coordinate tours to facilitate gaining a firsthand view of our industry.

8. *Guidance must refer to any state, regional, and local regulations currently in place.* Industry representatives at every grassroots meeting conveyed that water use, manure and biosolids use, and wild life are governed by another agency's regulations. Water use is restricted in every region, including what water source an industry operator can use, how much, and when. Federal EPA's Part 503 Rule promotes the use of biosolids for "maintaining or improving environmental quality and protecting public health." Wildlife management agencies in every region have strict provisions that make it impossible to restrict wildlife movement.

9. *Measures to permit rapid approvals for new technologies and new uses of existing technologies should be identified and implemented.* FDA, USDA, and EPA should review their approval processes for new technologies and new uses of existing technologies that address public health concerns associated with fresh produce.

10. *As the initiative moves forward to contemplate means to affect standards in countries importing to the U.S. market, it must do so in a manner consistent with free trade principles.* Forcing our trading partners to follow a document not based on science will inevitably be challenged as a non-tariff trade barrier.

11. *Through this and other components of the initiative it is imperative that the Agencies and the Administration clearly state the importance of increasing consumption of fresh fruits and vegetables.* At a time when incidence of chronic diseases such as cancer, heart disease, and high blood pressure, are on the rise and when an overwhelming number of scientific studies indicate that consumption of fresh fruits and vegetables (5 to 10 svgs/day) can decrease one's risk of many of these diseases, we must not jeopardize the public's health by inappropriately steering them away from fresh fruits and vegetables. Instead we must continue to support national initiatives that encourage increased consumption of fresh fruits and vegetables.

## SPECIFIC COMMENTS

Our comments that follow are specific to FDA's Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables.

### Preface

**Page 3:**

We recommend the term "good handling practices" be used in place of "good manufacturing practices" throughout the guide and initiative. Good manufacturing practices (GMPs) are codified regulations, whereas the guide is intended to be guidance. Using a term that is widely known as regulation in the context of federal guidance for fresh fruit and vegetable production is likely to be misinterpreted and confusing to regulatory officials, industry operators, and buyers.

**Page 3:**

Development of guidance for specific commodities is unnecessary. Instead of focusing government resources on developing commodity-specific guidance, we recommend that industry and government work in partnership, through a Memorandum of Understanding, to develop education and outreach programs based on broad FDA guidance. It is under this cooperative framework that we, together, can make a true impact on public health. After all, results, not words, will give consumers confidence.

### Introduction

**Page 5:**

We suggest the statement "although the reported incidence of foodborne infection from fresh produce is relatively low, *it is increasing*" be restated as "although the reported incidence of foodborne infection from fresh produce is relatively low, fresh produce has been increasingly found to be a vehicle of foodborne illness."

Clarifying that fresh produce is the *vehicle* of foodborne illness more accurately portrays the epidemiological information, and will minimize misinterpretation.

**Page 6:**

We recommend that the term "municipal biosolids" be used rather than "municipal sewage sludge." Municipal biosolids is a more contemporary term and more accurately portrays that it is the by - product of human waste digestion, not human waste, that is used for fertilizing.

## II. Water

**Section A. Microbial Hazard, Page 8:**

The epidemiological investigation of this *Salmonella* outbreak determined that GMP's were not being followed by the orange juice processor. Tree frogs, whose fecal matter contained *Salmonella*, were determined to be the likely cause of contamination. In fact, the surface water was not characterized as the source of contamination (1).

**Section B. Control of Potential Hazards, Page 9:**

Suggesting that "water quality may need to be greater for overhead spray irrigation than for drip irrigation" does not take into account the multiple and sometimes unforeseen forces that dictate irrigation methods.

We recommend replacing the above statement with "be aware that the potential for and extent of produce contamination by pathogens may be influenced by the source and method of irrigation employed. To prevent contamination, water used for irrigation should be of appropriate quality. To achieve the greatest potential impact on public health, efforts should be focused at the potential sources of contamination, not solely on interventions.

**Section 1.0 Agricultural Water, Page 10:**

Testing water sources to determine if they are "safe for intended use" is an insufficient safety management system due to the low probability of detection. Instead, testing should only be recommended to evaluate an intervention's effectiveness. For example, if water is chlorinated, testing to insure chlorine levels and pH are maintained appropriately may be warranted. However, testing municipal water sources to assure "sufficient quality" should not be a requirement and burden placed on individual operators.

The responsibility of assuring the quality of water, when using a public source, should not be that of individual operators. Because a number of factors could contribute to water source contamination, it is unreasonable for individual operators to have complete responsibility for testing and intervening, if necessary, to assure that water used for irrigation is "safe for the intended use." For example, if one operator found that river water was not of "sufficient quality," he would be obligated to intervene, as would all growers using the same source. Instead, the focus needs to be on addressing the **source** of contamination, such as contaminated effluent from an upstream sewage treatment plant, or feedlot runoff. This obligation should reside with the local, county, or state water district having jurisdiction, not the individual grower.

**Section 1.0 Agricultural Water, Page 11:**

We suggest omitting the statement "alternative application methods that reduce or avoid water-to-produce contact" as a control mechanism to ensure that water quality is sufficient for its intended use.

Growers do not have access to multiple water supplies. At every grassroots meeting the industry conveyed the explicit regulations governing water use, often including what water source an industry operator can use, how much, and when.

We suggest omitting the statement "delaying water use until quality improves" to ensure that water quality is sufficient for its intended use.

There is no room to maneuver when a crop needs water. While the guidance recognizes that the "feasibility of these, or other, controls will depend on the intended water use and the needs and resources of a particular operation," the recommendations are impractical. Rather than suggesting impractical and unproven intervention strategies, the quality of irrigation water should be assured by the overseeing water district. Advice absent of a public health impact will result in stretching resources without any additional assurance of food safety.

**Section 2.1 Wash Water, Page 15:**

The referenced research on tomatoes indicates that "*Salmonella* in a water bath may be rapidly internalized by tomatoes when the water bath temperature is colder than the tomatoes." Based on this study FDA guidance recommends that "wash water for tomatoes be hyperchlorinated and 10° F warmer than the tomatoes." We have two concerns with this recommendation:

- Promoting hyperchlorination to enhance food safety could have far reaching environmental implications that need to be considered.

- Maintaining water at a temperature greater than produce prevents what is often a grower's primary goal -- to remove field heat from the product.

Brian Haddix, of the California Grape and Tree Fruit League, stated at the Oregon grassroots meeting on December 12, that fruit picked in the summertime is often 105° F or greater requiring a 115° F wash bath temperature. This would not enable removal of field heat which preserves both the quality and safety of the produce.

We recommend that the statement read "this research shows the importance of maintaining water used in washing operations free from pathogens, so that no matter what temperature differential exists between the product and wash water, produce contamination is prevented."

## III. Manure and Municipal Sewage Sludge

**Section 2.2.1 Untreated Manure, Page 19:**

Specific application - to - harvest delay minimums for untreated and treated manure should not be set in the absence of sound science. Without this base any recommendations will not impact public health.

The guide refers to two scientific studies, one that was conducted in a test tube and another that has not yet been published. While both are important to the advancement of our understanding of pathogen survival in animal manure and signal the need for more research, neither is sufficient to base policy upon.

The industry agrees with the recommendation to "reduce the risk of contamination from manure by maximizing the time between application of manure to a field and harvest." However, we do not support referencing standards or practices that merely *exist* today but were not based on microbiological food safety concerns. For example, the statement that "intervals of ... 120 to 150 days between application and harvest of manure for stone fruit" was included based on a rhetorical question asked during the November 19, National Advisory Committee on Microbiological Criteria for Foods (NACMCF) meeting. We urge you to apply greater discrimination when developing recommendations and assure that they flow from scientific findings, not casual comment.

While it may seem that the industry opposes all recommendations as a means of minimizing burdensome regulation on the industry, that is not the case. We believe that through educated hypotheses and common sense there exists a starting point upon which to evolve as science becomes available. However, this information is not strong enough to base policy on. Rather, the short-term focus should be on education using a common sense approach and based on broad FDA guidance.

The suggestion to plan " crop rotations where manure is applied to fields planted with crops that are to be cooked or properly heat processed prior to being delivered to consumers" does not have broad industry application. It does not account for commodities in which multiple crops are grown each season nor for other forces that may prohibit this type of crop rotation.

**Section 3.0 Animal Feces, Page 21:**

High concentrations of wildlife are undesirable to the industry as well as public health officials because they consume produce and because their feces may carry pathogens that could potentially contaminate product. However, at the grassroots meetings it became clear that wildlife management agencies often times prohibit growers from intervening. For example, the Department of Natural Resources in New York State manages the deer population and will not allow public intervention. In Florida one grower was prohibited from trying to remove a bear and her cubs from his orchard by the overseeing wildlife management agency.

It must be recognized that other agency's recommendations could be in direct conflict with this guidance and must be considered.

## IV. Sanitation and Hygiene

### Section 2.1 Personal Health, Page 22:

The guidance states "it is suggested that operators train employees to report to the person in charge any information about their health or activities as they relate to diseases that are transmissible through food" and that "workers should be taught to report symptoms caused by illness, infection, or other source that is associated with..." While the intentions are sound and make sense, it is unlikely to work both from an industry operator and farm worker perspective. Throughout the grassroots meetings this was posed as a significant issue by extension agents, industry operators, and the United Farm Workers because:

- The industry must respect the privacy of their workers.
- Workers are afraid to convey health information for fear of being fired or retaliated against.
- Workers cannot afford to miss a day of work, prohibiting them from declaring any illness.

### Section 2.3 Harvesting Precautions, Page 26:

At the November 19, NACMCF meeting CDC and other public health officials clearly stated that do not advocate glove use as a substitute for maintaining clean hands. Since, references in the guidance that employees use gloves have been omitted. However, we believe that glove use should not be recommended for anyone handling produce, including inspectors and buyers. Instead, handwashing should be recommended for all persons. Promoting one message, without exception, whether a federal recommendation or industry management decision, will result in greater compliance.

### Section D. Transportation, Page 30:

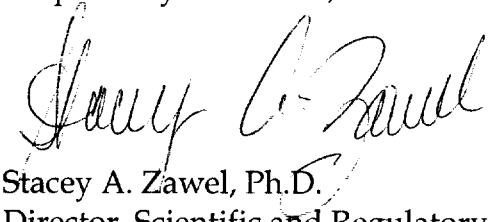
The draft guidance states that the U.S. Code of Federal Regulations requires that "storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination." While the produce industry agrees with this and recognizes their role in assuring that transportation vehicles are in the appropriate sanitation condition prior to loading, industry operators do not have control over the transportation link once it leaves their dock. Therefore, it is essential that the President's food safety initiative include focus on the transportation segment of the distribution chain in order to assure a seamless food safety system.

## V. Positive Lot Identification

**Page 31:**

It may seem simple to request that growers include tracking information on their packages, but without efforts by everyone in the distribution chain to maintain the product's identify no benefit will be achieved. Therefore we recommend that this challenge be approached differently. We encourage the Agencies to take advantage of the work that the industry, along with it's distribution partners, has already begun. *If* the inclination still exists to develop federal recommendations then we encourage the agencies to provide the leadership to work in partnership with all segments of the production and distribution chain to effectively address this challenge.

Respectfully submitted,



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